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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 08/985,007 | 12/04/97 | MIURA | N 2550/KIP |

| EXAMINER | |
|---|---|
| CHIN, C | |
| **ART UNIT** | **PAPER NUMBER** |
| 1641 | 10 |

**DATE MAILED:** 08/17/99

HM22/0817
SHAHAN ISLAM FRIEDMAN SIEGELBAUM
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 08/985,007 | Miura et al |
| **Examiner** | **Group Art Unit** |
| C. Chin | 1641 |

***—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—***

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

☒ Responsive to communication(s) filed on 5/27/99.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

**Disposition of Claims**

☒ Claim(s) 13-27 is/are pending in the application.

Of the above claim(s) 13 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 14-27 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119 (a)-(d)**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

**Attachment(s)**

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

**Office Action Summary**

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the antigen fixed to another surface of the metal film as recited in claims 20 and 23 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

### *Claim Rejections - 35 U.S.C. § 112*

2. Claims 14-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is vague and confusing. The last line of the claim is not clear as to whether the antigen fixed to the resonance material is the "medical substance" or a reagent for detection of the "medical substance". If the antigen is the "medical substance", then the claimed apparatus is essentially a "used apparatus" because the "medical substance" is already present on the resonance material and thus cannot be used to assay a sample to determine the amount of medical substance in the sample as set forth in the preamble of the claim. If the antigen is the "medical substance", then a corresponding antibody specific for the antigen would have to be present on the resonance material to permit detection of the antigen. If the antigen is a reagent for detection of a medical

substance, then the claim should be amended to state that the antigen is specific for the medical substance.

Claims 19-21 are vague and confusing because they depend from canceled claim 2.

Claim 20 is further vague and confusing as it is not clear as to how the antigen can be fixed to a surface of the metal film which is opposite to the surface prism when the metal film is formed on the surface of the prism. The claim fails to recite the presence of another metal film that is positioned opposite the metal film on the surface of the prism to support the antigen.

Claim 22 suffers from the same deficiency as claim 14.

Claim 23 suffers from the same deficiency as claim 20.

Claim 24 is vague and confusing. In lines 4-5, is the antigen the "medical substance" or a reagent for detection of the "medical substance"? If the antigen is the "medical substance", then a corresponding antibody specific for the antigen would have to be present on the resonance material to permit detection of the antigen. Lines 6-7 are confusing as it appears to recite that the antibody is coupled to the "medical substance" and to the sample? Furthermore, is the antibody specific for the antigen or the "medical substance"? Lines 8-9 are confusing the recitation of "the mixture" lacks antecedent support and are redundant as it appears that sample and antibody were already contacted with the resonance material in lines 4-7. Lines 11-12 are vague because any change in the properties of the incident light is the result of "medical substance" and/or antibodies being bound to the resonance material which is not clearly set forth in the detection step recited in these two lines.

***Claim Rejections - 35 U.S.C. § 102***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 14, 15, 17, 19, 22, 24, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Batchelder et al (U.S. Patent 4,844,613).

See paper #7 for a discussion of the specific components of the apparatus disclosed in the Batchelder et al reference. Additionally, as shown in Figure 1, the light from source (15) is incident on the prism in the form of a divergent beam. This beam, after refraction at the glass/metal interface passes back through the prism to a detector array (16). The image seen by the array comprises a substantially uniformly illuminated area with a dark band corresponding to the angle or angles at which plasmon resonance reduces the intensity of reflected light. The position of the absorption band may be determined by a microprocessor coupled to the detection array (16) (col. 2, lines 34-44).

Applicants have characterized their invention and noted differences between the instant invention and the sensor of Batchelder et al on pages 9-10 of their amendment. As set forth above in the 112 second paragraph rejections, the instant claims do not reflect how Applicants have characterized their invention, specifically, the claims do not clearly claim the presence of an antigen on the resonance material wherein the antigen is the analyte that is to be detected. As far as anyone of ordinary skill in the art can tell, the instant claims read on what Applicants consider

to be a sensor that relies upon "conventional detecting technology" such as the sensor of Batchelder et al.

5. Claims 14, 15, 17, 19, 22, 24, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Finlan et al (U.S. Patent 4,997,278).

See paper #7 for a discussion of the specific components of the apparatus disclosed in the Finlan et al reference. Additionally, Finlan et al teaches monitoring changes in the angle of incidence of light from the source to monitor changes in resonance caused by the presence of analyte (col. 1, lines 51-68, and col. 2, lines 1-10).

Applicants have characterized their invention and noted differences between the instant invention and the sensor of Finlan et al on pages 9-10 of their amendment. As set forth above in the 112 second paragraph rejections, the instant claims do not reflect how Applicants have characterized their invention, specifically, the claims do not clearly claim the presence of an antigen on the resonance material wherein the antigen is the analyte that is to be detected. As far as anyone of ordinary skill in the art can tell, the instant claims read on what Applicants consider to be a sensor that relies upon "conventional detecting technology" such as the sensor of Finlan et al.

6. Claims 14, 15, 17, 19, 22, 24, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Finlan et al (U.S. Patent 5,047,213).

Applicants have characterized their invention and noted differences between the instant invention and the sensor of Finlan et al on pages 9-10 of their amendment. As set forth above in the 112 second paragraph rejections, the instant claims do not reflect how Applicants have characterized their invention, specifically, the claims do not clearly claim the presence of an antigen on the resonance material wherein the antigen is the analyte that is to be detected. As far as anyone of ordinary skill in the art can tell, the instant claims read on what Applicants consider to be a sensor that relies upon "conventional detecting technology" such as the sensor of Finlan et al.

7. Claims 14, 16, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart.

Stewart (U.S. Patent 5,229,833) discloses an optical sensor for performing immunoassays. The sensor includes a resonant mirror device (1) and a prism (2) disposed adjacent to each other for coupling a beam of light into the mirror device (1). The mirror device (1) and prism (2) are mounted on a rotatable platform. A beam of light is produced by a He-Ne laser (3) and is linearly polarized with equal TE and TM components by a polarizer (4) arranged at 45 degrees to TE and TM axis. A lens (6) is arranged in the path of the linearly polarized beam of light for focussing the beam of light onto the mirror device (1) thereby providing simultaneously a range of angles of incidence at which the beam of light can be coupled into the mirror device (1) (see Figure 1). When the mirror device is illuminated with a collimated beam from the laser, a resonance will

occur at one particular wavelength. This wavelength can be monitored for testing a sample (col. 4, lines 34-56).

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,491,556

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
August 15, 1999

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641